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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; SALIX PHARMACEUTICALS, INC.; PROGENICS PHARMACEUTICALS, INC.; and WYETH LLC, formerly known as WYETH, Plaintiffs, v. ACTAVIS LLC; ACTAVIS, INC.; ACTAVIS ELIZABETH LLC; and ALLERGAN PLC formerly known as ACTAVIS PLC, Defendants.	Civil Action No. 15-8353 (SRC) (CLW) *Document Electronically Filed*

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals International, Inc. ("Valeant"), Salix Pharmaceuticals, Inc. ("Salix"), Progenics Pharmaceuticals, Inc. ("Progenics"), and Wyeth LLC (collectively, "Plaintiffs") by way of Amended Complaint against Defendants Actavis LLC, Actavis, Inc., Actavis Elizabeth LLC, and Allergan plc (collectively "Actavis" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Valeant is a corporation organized and existing under the laws of Canada. Its United States headquarters are located at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

2. Plaintiff Salix is a corporation organized and existing under the laws of California, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, NC 27615. Salix is the registered holder of approved New Drug Application No. 021964, which covers Relistor®.

3. Plaintiff Progenics is a corporation organized and existing under the laws of Delaware, having its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware LLC, having places of business at 235 East 42nd Street, New York, NY 10017, and Five Giralda Farms, Madison, NJ 07940.

5. Upon information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

6. Upon information and belief, Defendant Actavis, Inc. is a corporation organized and existing under the laws of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

7. Upon information and belief, Defendant Actavis Elizabeth LLC is a single-member limited liability company organized and existing under the laws of Delaware, having a place of business at 200 Elmora Avenue, Elizabeth, New Jersey.

8. Upon information and belief, Defendant Allergan plc, f/k/a Actavis plc, is a publicly-traded company organized and existing under the laws of Ireland, having its corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland, and U.S. administrative headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

9. Upon information and belief, Actavis Elizabeth LLC is wholly owned by Actavis LLC. Upon information and belief, Actavis LLC is wholly owned by Actavis US Holding LLC. Upon information and belief, Actavis US Holding LLC is wholly owned by Actavis, Inc. Upon information and belief, Actavis, Inc. owns Actavis LLC and Actavis Elizabeth LLC through its ownership of other entities. Upon information and belief, Allergan plc is the global parent of, *inter alia*, Actavis LLC, Actavis Elizabeth LLC, and Actavis, Inc.

NATURE OF THE ACTION

10. This is an action for infringement of United States Patent Nos. 8,247,425 ("the '425 patent"); 8,420,663 ("the '663 patent"); 8,552,025 ("the '025 patent"); 8,822,490 ("the '490 patent"); and 9,180,125 ("the '125 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Actavis's filing of an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic methylnaltrexone bromide formulation for subcutaneous injection, 12 mg/0.6 mL and 8 mg/0.4 mL ("Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection").

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. Upon information and belief, this court has jurisdiction over Actavis LLC. Upon information and belief, Actavis LLC is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis LLC directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection. Upon information and belief, Actavis LLC's principal place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis LLC is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

13. Upon information and belief, this court has jurisdiction over Actavis, Inc. Upon information and belief, Actavis, Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis, Inc. directly, or indirectly, manufactures, markets, and sells generic drug products, including generic products manufactured by Actavis LLC, throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection. Upon information and belief, Actavis, Inc.'s principal place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Upon information and belief, Actavis, Inc. is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

14. Upon information and belief, this court has jurisdiction over Actavis Elizabeth LLC. Upon information and belief, Actavis Elizabeth LLC is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Actavis Elizabeth LLC directly, or indirectly, manufactures, markets, and sells generic drug products, including generic products manufactured by Actavis LLC, throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection. Upon information and belief, Actavis Elizabeth LLC's principal place of business is at 200 Elmora Avenue, Elizabeth, New Jersey. Upon information and belief, Actavis Elizabeth LLC is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

15. Upon information and belief, this court has jurisdiction over Allergan plc. Upon information and belief, Allergan plc is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Allergan plc directly, or indirectly through its wholly owned subsidiaries, manufactures, markets, and sells generic drug products, including generic drug products manufactured by Actavis LLC, throughout the United States and in this judicial district, and this judicial district is a likely destination for Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection. According to Allergan plc's Form 10-Q, filed November 6, 2015, "Allergan plc is a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of brand name [], medical aesthetics, generic, branded generic, biosimilar and over-the-counter [] pharmaceutical products." Upon information and belief, Allergan plc purposefully has conducted and continues to conduct business in this

judicial district.

16. Upon information and belief, Actavis LLC, Actavis, Inc., Actavis Elizabeth LLC, and Allergan plc operate as a single integrated business. Upon information and belief, Allergan plc's Form 10-Q, dated November 6, 2015, and Form 10-K, filed February 18, 2015, indicate that it files a single financial report to the SEC for itself and its subsidiaries. Upon information and belief, Allergan plc, Actavis Elizabeth LLC, and Actavis, Inc. share at least one corporate officer.

17. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

18. The U.S. Patent and Trademark Office ("PTO") issued the '425 patent on August 21, 2012. The '425 patent claims, *inter alia*, prefilled syringes comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '425 patent and have the right to sue for infringement thereof. A copy of the '425 patent is attached hereto as Exhibit A.

19. The PTO issued the '663 patent on April 16, 2013. The '663 patent claims, *inter alia*, methods of using compositions of methylnaltrexone. Plaintiffs hold all substantial rights in the '663 patent and have the right to sue for infringement thereof. A copy of the '663 patent is attached hereto as Exhibit B.

20. The PTO issued the '025 patent on October 8, 2013. The '025 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the '025 patent and have the right to sue for infringement thereof. A copy of the '025 patent is attached as Exhibit C.

21. The PTO issued the '490 patent on September 2, 2014. The '490 patent claims, *inter alia*, packaged compositions comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '490 patent and have the right to sue for infringement thereof. A copy of the '490 patent is attached hereto as Exhibit D.

22. The PTO issued the '125 patent on November 10, 2015. The '125 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '125 patent and have the right to sue for infringement thereof. A copy of the '125 patent is attached hereto as Exhibit E.

23. Salix is the holder of New Drug Application ("NDA") No. 021964 for Relistor®, which the FDA approved on April 24, 2008, (12 mg/0.6 mL prefilled syringe for subcutaneous injection) and September 27, 2010 (8 mg/0.4 mL prefilled syringe for subcutaneous injection). In conjunction with NDA No. 021964, the '425 patent, '663 patent, '025 patent, '490 patent, and '125 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

24. Methylnaltrexone bromide formulations for subcutaneous injection, 8 mg/0.4 mL and 12 mg/0.6 mL, are sold in the United States under the trademark Relistor®.

ACTAVIS'S INFRINGING ANDA SUBMISSION

25. Upon information and belief, Actavis filed or caused to be filed with the FDA ANDA No. 208112, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

26. Upon information and belief, Actavis's ANDA No. 208112 seeks FDA approval to sell in the United States Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection, intended to be a generic version of Relistor®.

27. Salix, Progenics and Wyeth LLC received a letter from Actavis LLC dated

October 27, 2015, purporting to be a Notice of Certification for ANDA No. 208112 ("Actavis's first notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95(c). Actavis's first notice letter was addressed to Wyeth LLC at Madison, NJ.

28. Salix and Wyeth LLC received a letter from Actavis LLC dated January 8, 2016, purporting to be a Notice of Certification for ANDA No. 208112 ("Actavis's second notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95(c). Actavis's second notice letter was addressed to Wyeth LLC at Madison, NJ.

29. Actavis's first notice letter and second notice letter allege that Actavis has submitted to the FDA ANDA No. 208112 seeking FDA approval to sell Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection, intended to be a generic version of Relistor®.

30. Actavis's first notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any valid claims of the '425, '663, '025, and '490 patents.

31. Actavis's second notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any valid claims of the '125 patent.

32. Upon information and belief, ANDA No. 208112 seeks approval of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection that is the same, or substantially the same, as Relistor®.

33. Upon information and belief, Actavis LLC's actions related to ANDA No. 208112 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Actavis, Inc., Actavis Elizabeth LLC, and Allergan plc.

COUNT I AGAINST ACTAVIS

Infringement of the '425 Patent under § 271(e)(2)

34. Paragraphs 1-33 are incorporated herein as set forth above.

35. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '425 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208112 seeking approval for the commercial marketing of Actavis's' generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '425 patent.

36. Upon information and belief, Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '425 patent.

37. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

COUNT II AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '425 Patent

38. Paragraphs 1-37 are incorporated herein as set forth above.

39. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

40. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

41. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone

bromide formulation for subcutaneous injection before the expiration date of the '425 patent, including Actavis's filing of ANDA No. 208112.

42. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

43. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '425 patent.

COUNT III AGAINST ACTAVIS

Infringement of the '663 Patent under § 271 (e)(2)

44. Paragraphs 1-43 are incorporated herein as set forth above.

45. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '663 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208112 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '663 patent.

46. Upon information and belief, Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '663 patent.

47. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

COUNT IV AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '663 Patent

48. Paragraphs 1-47 are incorporated herein as set forth above.

49. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

50. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

51. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '663 patent, including Actavis's filing of ANDA No. 208112.

52. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

53. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '663 patent.

COUNT V AGAINST ACTAVIS

Infringement of the '025 Patent under § 271(e)(2)

54. Paragraphs 1-53 are incorporated herein as set forth above.

55. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '025

patent by submitting, or causing to be submitted to the FDA, ANDA No. 208112 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '025 patent.

56. Upon information and belief, Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the '025 patent.

57. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe and/or contributorily infringe at least one claim of the '025 patent.

COUNT VI AGAINST ACTAVIS

Declaratory Judgment of Infringement of the '025 Patent

58. Paragraphs 1-57 are incorporated herein as set forth above.

59. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

60. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

61. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '025 patent, including Actavis's filing of ANDA No. 208112.

62. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide formulation for

subcutaneous injection will directly infringe and/or contributorily infringe at least one claim of the ’025 patent.

63. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the ’025 patent.

COUNT VII AGAINST ACTAVIS

Infringement of the ’490 Patent under § 271(e)(2)

64. Paragraphs 1-63 are incorporated herein as set forth above.

65. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the ’490 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208112 seeking approval for the commercial marketing of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the ’490 patent.

66. Upon information and belief, Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the ’490 patent.

67. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’490 patent.

COUNT VIII AGAINST ACTAVIS

Declaratory Judgment of Infringement of the ’490 Patent

68. Paragraphs 1-67 are incorporated herein as set forth above.

69. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and

2202.

70. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

71. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the '490 patent, including Actavis's filing of ANDA No. 208112.

72. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '490 patent.

73. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the '490 patent.

COUNT IX AGAINST ACTAVIS

Infringement of the '125 Patent under § 271(e)(2)

74. Paragraphs 1-73 are incorporated herein as set forth above.

75. Under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '125 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208112 seeking approval for the commercial marketing of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '125 patent.

76. Upon information and belief, Actavis's generic methylnaltrexone bromide

formulation for subcutaneous injection will, if approved and marketed, infringe at least one claim of the ’125 patent.

77. Upon information and belief, Actavis will, through the manufacture, use, import, offer for sale, and/or sale of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’125 patent.

COUNT X AGAINST ACTAVIS

Declaratory Judgment of Infringement of the ’125 Patent

78. Paragraphs 1-77 are incorporated herein as set forth above.

79. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

80. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

81. Actavis has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration date of the ’125 patent, including Actavis’s filing of ANDA No. 208112.

82. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’125 patent.

83. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Actavis’s generic methylnaltrexone

bromide formulation for subcutaneous injection will constitute infringement of at least one claim of the ’125 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Actavis on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the ’425 patent by submitting or causing to be submitted ANDA No. 208112 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the ’425 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the ’663 patent by submitting or causing to be submitted ANDA No. 208112 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the ’663 patent;

3. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the ’025 patent by submitting or causing to be submitted ANDA No. 208112 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis’s generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the ’025 patent;

4. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the ’490 patent by submitting or causing to be submitted ANDA No. 208112 to the

FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '490 patent;

5. enter judgment that, under 35 U.S.C. § 271(e)(2), Actavis has infringed at least one claim of the '125 patent by submitting or causing to be submitted ANDA No. 208112 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection before the expiration of the '125 patent;

6. order that that the effective date of any approval by the FDA of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection be a date that is not earlier than the expiration of the '425 patent, '663 patent, '025 patent, '490 patent, and '125 patent or such later date as the Court may determine;

7. enjoin Actavis from the commercial manufacture, use, import, offer for sale, and/or sale of Actavis's generic methylnaltrexone bromide formulation for subcutaneous injection until expiration of the '425 patent, '663 patent, '025 patent, '490 patent, and '125 patent or such later date as the Court may determine;

8. enjoin Actavis and all persons acting in concert with Actavis from seeking, obtaining, or maintaining approval of Actavis's ANDA No. 208112 until expiration of the '425 patent, '663 patent, '025 patent, '490 patent, and '125 patent;

9. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

10. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: February 18, 2016
Newark, New Jersey

Respectfully submitted,

s/ Elvin Esteves
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Attorneys for Wyeth LLC

CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

Dated: February 18, 2016
Newark, New Jersey

By: s/ Elvin Esteves

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